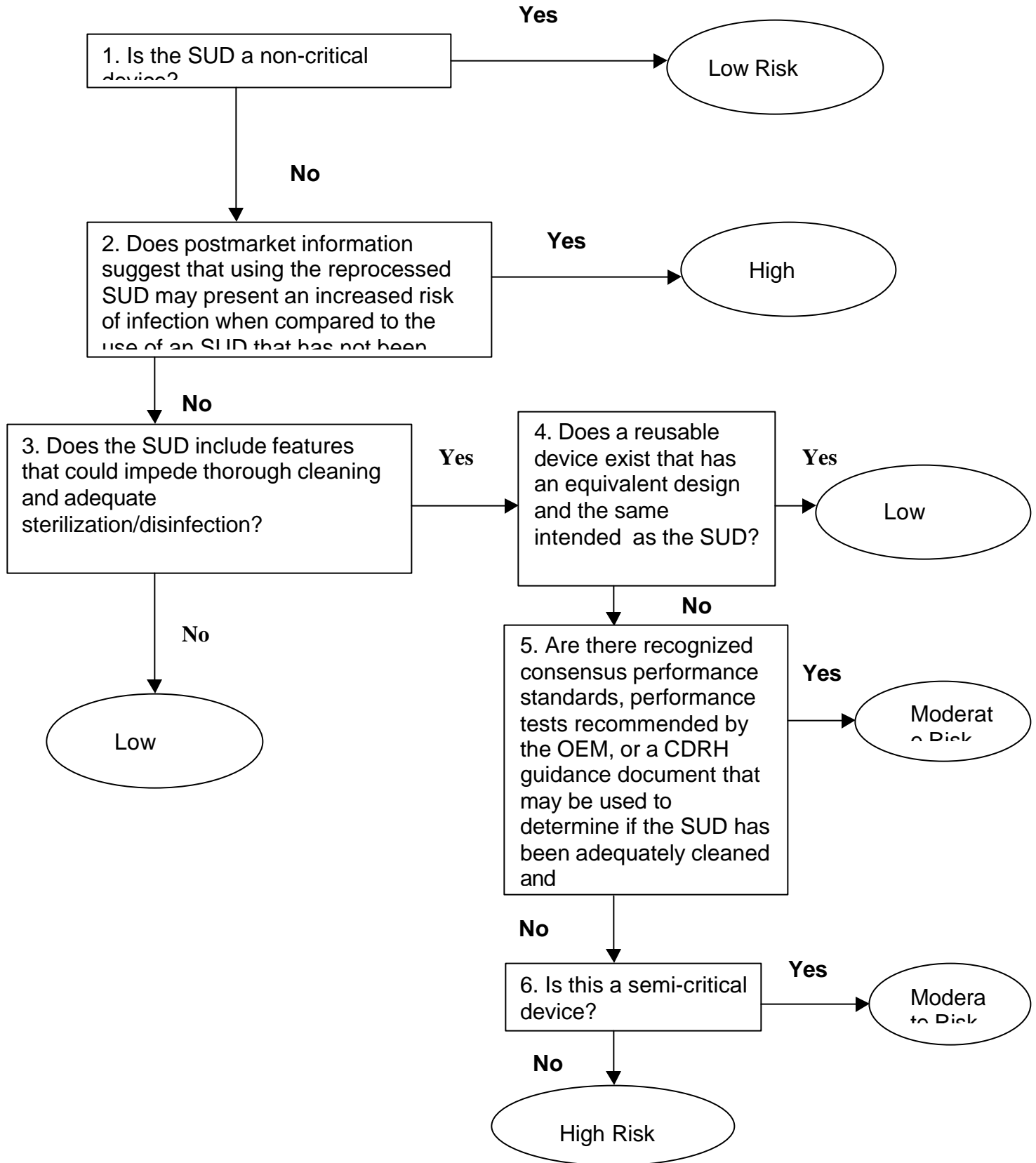
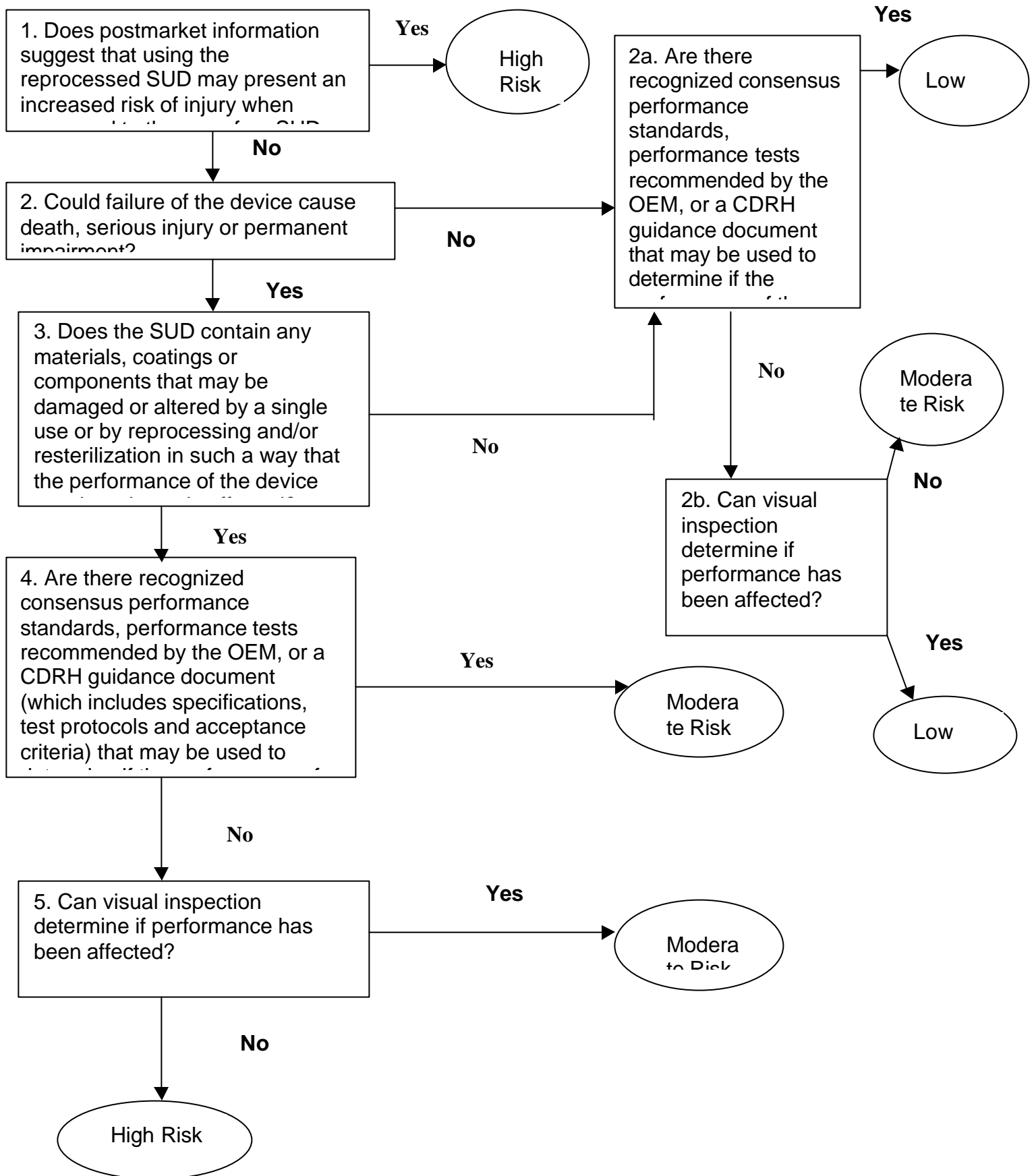


Handout 1

Flowchart 1 – Infection Risk



Flowchart 2 – Inadequate Performance Risk



Work Sheet

1. Is the SUD an implant as defined in 21 CFR Part 860.3(d)?

Yes or NO

If the answer to question #1 above is Yes, STOP. SUD is categorized as High Risk.

2. What is the risk of infection according to Flowchart 1?

Low Risk or Moderate Risk or High Risk

If the answer to question #2 is High Risk, STOP. SUD is categorized as High Risk.

3. What is the risk of inadequate performance according to Flowchart 2?

Low Risk or Moderate Risk or High Risk

If the answer to question #3 is High Risk, STOP. SUD is categorized as High Risk.

4. Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.

5. Did the SUD result in a Low Risk on Flowcharts 1 AND 2? If so, the SUD is low risk.

Please circle appropriate risk categorization below.

Low Risk or Moderate Risk or High Risk